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ADVERSE REACTIONS FOLLOWING VACCINATION

CLINICAL PICTURE, MANAGEMENT, INVESTIGATION, REPORTING.

NATIONAL IMMUNISATION MISSION
Directorate General of M.H. & F.W.
Uttar Pradesh

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FOREWORD

The hand book, Second of Documentation Series is being broughtout on "Adverse Reactions Following Vaccinations" is based on similar document released by National Immunization Mission, Ministry of Health & Family Welfare, Govt. of India.

In a programme of this magnitude (number of beneficaries and for flung areas spread from Himalayas to Vindhyas) adverse reactions is a possibility which should be attended and investigated on sound technical ground.

The Booklet will prove useful to Senior Health Administraters in investigating & studing the serious adverse reactions. The experiences gained will be utilized to prevent such incidences through Careful planing & High Quality Service.

DIRECTOR
FAMILY WELFARE
UTTAR PRADESH

ADVERSE REACTIONS FOLLOWING VACCINATION

1. INTRODUCTION

1.1 Reactions Inherent to vaccination

The reactions that commonly follow vaccination are mild fever, redness, tenderness and pain at the site of injection. Fever and rash on the 6th or 7th day after measles vaccination has also been reported. Despite the safety of vaccines serious complications can also occur. Although their rates are difficult to estimate precisely, it is known that they are a mere fraction compared to the complication ratio arising out of the diseases themselves. The estimated rates are shown below:

Estimated Rates of Adverse Reactions

Vaccine	Adverse reactions	Complication Rate/ 100,000	
		Disease (Cases)	Vaccine (Immunizations)
1	2	3	4
DPT	Permanent brain damage	600-2000	0.2-0.6
	Death	100-4000	0.2
	Encephalopathy/ Encephalitis(Including seizures focal neurelogical signs, coma ,Raye's syndrome)	90-4000	0.1-3.0

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1	2	3	4
	Convulsions	600-8000	0.3-90
	Shock	-	0.5-30
MEASLES	Encephalitis/ Encephalopathy	50-400	0.1
	Subacute sclerosing-panencephalitis	0.5-2.0	0.05- 0.1
	Pneumenia	3800-7300	-
	Convulsions	500-1000	0.02-190
	Death	10-10000	0.02-0.3
BCG	Disseminated BCG infection	-	0.1
	Ostoitis/ ostemyelitis	-	0.1-30
	Suppurative adenitis (children under 2 Years)	-	100-4300

(Source : WHO Chronicle 1984, 38, 3:95-98)

Paralytic poliomyelitis is the only serious adverse reaction associated with OPV. The risk is increased in immuno-deficient children. In a 10 year WHO collaborative study, the risk of vaccine associated paralysis was estimated to be about 1 case per million vaccine and the risk of a close contact of a vaccine developing paralytic polio was 1 case per approximately 5 million doses distributed.

1.2 Complications due to faulty techniques

Complications due to faulty techniques are avoidable if guidelines for administering the vaccine are followed. In this country, the complications arising out of faulty techniques are the main problems as opposed to the inherent risks.

1.2.2 Abscesses

The most common complication is the formation of absecesses following the use of in adequately sterilized syringes and needles[11]: Absesses require prompt attention from the Medical Officers. In rare instances, in the absence of adequate medical care such abseesses can lead to death.

1.2.2 Post-measles vaccination complications

Fever, Profuse watery diarrhoea and vomiting with in a few hours of measles vaccine administration have been reported. The case fatality rate in these incidents was high with death occuring within 24 to 48 hours after the onset of symptoms. Although the precise cause of the symptoms and deaths has not been indentified the most likely reason appears to be contamination of the vial of measles vaccine. The symptoms of watery diarrhoea, vomiting and fever within a few hours of vaccination and death in 24 to 48 hours after the onset of symptoms reported in these incidents are suggestive of **TOXIC SHOCK SYNDROME.** In the

incidents investigated the quality of the services was poor with high probability of contamination of the vaccine vials.

1.3 Temporal association

The vaccines are usually administeredi to children at an age when infections are common. Some of the reactions reported may have only a temporaly relationship to vaccination, the primary cause being unrelated to vaccine administration. Investigations are necessary to establish the causal relationship. It is important that children of the same age group in the area who did not receive vaccines are also examined.

Some conditions, particularly fever and neurological syndromes, also occur spontaneously among unimmunized children. Against the background of disease, it is sometimes difficult to determine if a recent immunzation is causally or merely coincidently related to illness. Convulsions for example, may follow DPT or measles immunization, but the background rate is high. At ages 3-15 months, the monthly incidence rate of convulsions ranges from 0.6 to 1.4/1000 children (WHO chronicle 1984, 38, 3:95-98).

2. TOXIC SHOCK SYNDROME

Toxic shock syndrome typically begins with high fever, vomiting, and profuse watery diarrhoea, sometimes accompanied by sore-throat, headache, and myalgias. The disease progresses to hypotensive shock with in 48 hours, and the patient develops a diffuse macular, erythematous rash with non purullent conjunctivitis. Patients may be disoriented and cardiac and multi-organ dysfunctions may also be seen, Symptoms often include alterations in the level of consciousness, oliguria and hypotension which in severe cases may progress to shock and disseminated intravascular coagulation. Recovery occurs within 7-10 days and is associated with desquamation, particulary of palms and soles, hair and nail loss has also been reported follwoing recovery. In the recovery phase there is desquamation of at least the palms, soles, or digits and often of other skin areas as well.

Laboratory studies reveal elevated blood urea nitrogen, serum creatinine bilirubin, and creatine phosphokinase levels and white blood cell counts with marked left shifts. Platelet counts are low in the first week of illness but are usually high in the second week. A number

of nonspecific laboratory abnormalities are present reflecting involvement of multiple organ systems including the hepatic, renal, muscular, gastrointestinal cardiopulmonary and central nervous system. Cultures performed prior to administration of antibiotic usually yield Staphylococcus aureus.

3. MEASURES TO MINIMIZE RISKS

The following measures need to be ensures to minimize risks of adverse events following vaccination:

-Training programmes for all categories of personnel should receive the highest priority to ensure high quality of services.

-Vaccination sessions should be held on fixed days. The children should be collected at the subcentre or at a central point in the village. Door-tO-door vaccination should not be conducted as such a strategy carries a high risk of break in the cold chain and contamination of the syringes and needles.

-Procedures for sterilization of syrignes and needles should be scrupulously followed and monitored. Wherever feasible steam sterilization should be given preference over boiling.

-use of a single sterile syringe and a single sterile needle for each injection.

-Issue of the vaccine to the field staff should be strictly monitored. Only required quantities of the vaccines should be taken from the PHC on the day of the sesson. Vaccines may be taken on the previous day only if **these are carried in vaccine carrier with four fully frozen icepacks.** Supervision should include measures to ensure that vaccine vials are **not stored in the periphery and re-used subsequently.** Batch number and expiry date of each vial should be recorded before issue.

-Measles vaccine should be reconstituted with the diluent provided with the vaccine. The diluent should be cooled before use. The vaccine should be kept on ice while in use. The children should be administered 0.5 ml of the vaccine in the arm subcutaneously. A separate sterile syringe and needle should be used for each injection.

-Vaccines should be discarded at the end of the session. Opened vial of vaccine **should not be reused under any circumstances.**

-Potentially harmful injectible drugs should be kept separate from vaccine vials and diluent.

-Field monitoring of the services must be regular so that any deficiencies could be noted and corrected in time. Reporting of abcesses by the health workers in their areas should be made compulsory.

The post of the District Immunization Officer was specially created to improve planning managemeent and field supervision of the immunization programme. The DIOs should be responsible for ensuring regular and adequate field supervision and for maintaining quality of the services. Plans should be realistic Critical analysis of the available resources should be made and the plans should take into consideration the logistics of vaccines and other supplies.

4. INVESTIGATION TEAMS.

4.1 District Investigation Team

Senior Medical Supdt.-Dist.Hosp.Convenor
Senior Pedritician - Dist.Hosp.-convenor
Senior Pathologist -District Hospital
Senior Physician - District Hospital.

The Team should visit the place of occurence PHC/Distt.Hospital within 6 Hours of the receipt of information.

4.2 Divisional Investigation Team

Additional Director Division - Convenor

Member

Head of Dept. or his nominee from

- Microbiology
- Pediatrics
- Medicine

The Team should visit the place of occurance PHC/Distt.Hospital within 72 hour of incidence

4.3 The Technical Teams should investigate any serious incident within 6 to 72 hours of its occurence. The report of the Team should be looked into by an independent referral group at state level.

4.4 The Medical Officer should inform about the incident to the C.M.O. immediately by Radiogram/Special messenger.

The C.M.O. should inform the Additional Director & State HQ immediately & proceed along Dist. Team to the site.

The CMO should issue a note giving the salient points or a letter which should be available to the press for publication. This popular version of the incident should be issued within 72 hours of the incident.

Copies of the full investigation report and comments of the referral group should be sent to the Ministry of Health and Family Welfare. Govt. of India through Directorate.

5. INVESTIGATION OF ADVERSE EVENTS

5.1 Field investigation and analysis of reports.

The basic principles of field investigation of outbreaks can be adopted for the investigation of adverse events. The first principle is to example the cases to confirm diagnosis. All children immunized du ng the particular session should klbe followed up and relevent details entered in the list given in Form I page 10. It is important that non-immunized children of the same age group in the localty are also examined to rule out temporal relationship. The details of the children vaccinated may be summarised as given in table below.

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Number of children vaccinated, with reactions and number of deaths

Date of vaccination:

Vaccine	Number vaccinated	No. with reaction	Dates(s) reaction	No.died	Date(s) of death

5.2 Operational aspects of the programme need to be carefully reviewed with special reference to procedures followed for collection, storage and issue of vaccines, methods adopted for the sterilization of syringes and needles (including the total quantities of syringes and needles available for a session) and frequency and quality of routine field and monitoring of services.

5.3 Where the adverse events are unexpected and easily explainable, it is important that the signs and symptoms of each cases are carefully noted. The promptness and completeness of investigations is of prime importance.

5.4 Vaccine samples should be sent for testing to the Natinal Control Laboratory. The samples should be well packed in ice and sent by a courier.

The forwarding note should clearly state the circumstances under which the sample(s) are sent. It is important that the **used vial with remaining vaccine is sent for testing alongwith unused vials of the same batch.**

5.5 Write-up and report results

A report should be prepared detailing the investigations conducted. This report should start with general information regarding the place where the events occurred. The name of the state, district and PHC/ward should be clearly stated. The following points should be covered in such a report:

5.5.1. Cases :

-How and when the first symptoms were observed and who reported the event;

-Who conducted the investigations and when were they started;

-How were the investigations conducted;

-Number of children vaccinated and the type of reactions observed. The line list and summary tables should be attached with the report;

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-Whether any children of the same age group in the area, who were not vaccinated, had similar symptoms.

5.5.2. Clinical aspects:

-detailed clinical picture;

-treatment provided to the children;

-outcome of illness;

-diagnosis by clinicians and laboratories if any, made by them.

5.5.3 Operational aspects:

-how are immunization services generally provided in the area. Procedure followed on the day of the event;

-when and from where the vaccines were received. How were the vaccines stored and transported;

-how many syringes and needles were available and procedures followed for the sterlization of the equipment.

-who administered the vaccines and the training they received.

-have similar reactions been observed in the past and were not reported.

5.5.4 Laboratory investigations:

Samples sent for testing and the names of the laboratories. The testing of the vaccine can take two to four months depending on the vaccine and the tests From II page 11.

5.5.5 Suggestions and recommendations

-what was the likely cause of the adverse event.

-measures recommended to minimise the risks in future.

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_____ _____

Date (Names & Designations)

LIST OF CASES WITH ADVERSE REACTIONS

Form-1

Sl. No.	Name	Address	Age	Sex	Vaccine Administered	Time of On Set	Date of Examination	Major sings & Symptoms	Diagnosis	Remarks

LABORATORY TESTING OF VACCINE VIALS

Form-II

Sl. No.	Vaccine	Manufactures	Batch No.	Date Vial Opened	Name of Laboratory	Report No.	Result	Remark of Testing laboratory if any

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